

REMARKS

The Examiner's Office Action mailed March 30, 2010, which rejected all pending claims, has been reviewed. Reconsideration in view of the foregoing amendments and remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of March 30, 2010, and submit that the following amendments and remarks are responsive to all points raised therein. Applicants believe that currently pending claims 1, 4, 9-11 are now in form for allowance.

Status of Claims

Claims 1, 4, 9-11 are pending in the application. Claims 2, 3, and 5-8 have been canceled. Claim 1 has been amended to incorporate the limitations of claim 3. New claim 11 has been added. Support for new claim 11 can be found for example at table 5 in the specification. No new matter has been added.

Rejection of Claims 1-5 and 7-10 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 1-5 and 7-10 under §103(a) as being unpatentable over Sherman (US 2003/0229101) in view of Vetter et al. (US 5808076) and Lange et al. (5152986).

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.' *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). See also *KSR*, 127 S.Ct. at 1734, 82 USPQ2d at 1391 ("While the sequence of these questions might be recorded in any particular case, the [Graham] factors continue to define the inquiry that controls.")

The present invention is directed to a solid pharmaceutical formulation that includes a quinolone antibiotic selected from the group consisting of pradofloxacin, a pradofloxacin salt or a hydrate of pradofloxacin or of its salt, 4 to 20 % by weight of a flavoring which is a mixture of proteins, fats, and carbohydrates, and, at least 1.5% to 15% by weight of colloidal silicon dioxide based on the total weight of the finished formulation. The ratio by weight of colloidal silicon dioxide to flavoring is 1:4 to 1:1. The formulation excludes starch.

Sherman teach ciprofloxacin tablets that include croscarmellose sodium and may include colloidal silicon dioxide. Sherman does not teach, as acknowledged by the Examiner, the addition of flavoring agents which are a mixture of proteins, fats, and carbohydrates, or that the quinolone is pradofloxacin. Vetter et al. and Lange et al. do not cure the deficiencies of Sherman et al. In particular, Vetter et al. and Lange et al. do not teach that the quinolone is pradofloxacin.

Amended claim 1 requires that the quinolone antibiotic has to be pradofloxacin, a pradofloxacin salt or a hydrate of pradofloxacin or of its salt, as such Sherman alone or in combination with Vetter et al. and Lange et al. can not render claim 1 obvious. Applicants request that the present rejection to claim 1 be withdrawn. Claims 4, 9, and 10, directly or indirectly, depend from claim 1, and as such Applicants request withdrawal of the present rejection with respect to claims 4, 9, and 10 as well.

Conclusion

Applicants respectfully submit that the pending claims are now in form for allowance.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,
/JESSICA MONACHELLO/
Jessica Monachello
Reg. No. 58,015
BAYER HEALTHCARE LLC
P.O. Box 390
Shawnee Mission, KS 66201
Tel: 913-268-2038
Fax: 913-268-2889